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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/062,838      | 01/31/2002  | Alfred E. Mann       | PD-0294 DIV         | 6151             |

23608 7590 02/26/2004

MEDTRONIC MINIMED INC.  
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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2.14

## Office Action Summary

### Application No.

10/062,838

### Applicant(s)

MANN ET AL.

### Examiner

Ann Y. Lam

### Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003 and 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 84-95 is/are pending in the application.
- 4a) Of the above claim(s) 56-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 84-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/20/04, 6/2/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 84-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 84 appears to claim an infusion system as well as a method. (Examiner will prosecute claims 84-95 as though they are claiming a method.)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 84 and 86-88 and 92-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Worthington et al., 5,822,715.

Worthington et al. discloses a method intended for use in an infusion device, the method comprising inputting externally supplied values and an estimate of a material to

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be ingested by the body into the programmer to estimate the bolus amount of fluid to be infused based upon the estimate of the material to be ingested by the body, wherein the externally supplied values and the estimate of the material to be ingested by the body are input using the at least one data input device (see column 14, lines 28-30); calculating an estimate of the bolus amount of fluid to be infused into the body based upon the externally supplied values and the estimate of the material to be ingested by the body (see column 14, lines 28-29); and providing the estimate of the bolus amount of fluid to the user for use with the infusion device (see column 14, lines 46-47.)

As to claim 86, there is at least one button (16) to interface with the processor (22).

As to claim 87, disclosed is the step of using the bolus estimator to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 6, lines 62-66.)

As to claim 88, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, (see column 14, lines 38-48.)

As to claim 92, the bolus estimator is considered to include a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. An on/off button for example is considered a lockout as claimed.

As to claims 93 and 94, the material to be ingested is carbohydrates (see column 14, line 47).

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As to claim 95, the method includes determining a duration of how long a previously infused amount of liquid will remain active in the body based upon a duration factor; and adjusting the estimate of the bolus amount of fluid to be infused based upon the determined duration, see column 5, lines 51-61.

3. Claims 84 and 86-88 and 91-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Franetzki et al., 4,282,872.

Franetzki et al. disclose a method intended for use in an infusion device, the method comprising inputting externally supplied values and an estimate of a material to be ingested by the body into the programmer to estimate the bolus amount of fluid to be infused based upon the estimate of the material to be ingested by the body (see column 3, lines 30-32), wherein the externally supplied values and the estimate of the material to be ingested by the body are input using the at least one data input device (2); calculating an estimate of the bolus amount of fluid to be infused into the body based upon the externally supplied values and the estimate of the material to be ingested by the body (see column 5, lines 59-61); and providing the estimate of the bolus amount of fluid to the user for use with the infusion device (see column 3, lines 65-68.)

As to claim 86, there is at least one button (2) to interface with the processor.

As to claim 87, disclosed is the step of using the bolus estimator to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 5, lines 51-61.)

As to claim 88, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, (see column 5, lines 57-61.)

As to claim 91, the step of programming the infusion device to infuse the estimate of the bolus amount of fluid into the body is disclosed, see column 5, line 55.

As to claim 92, the bolus estimator is considered to include a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. An on/off button for example is considered a lockout as claimed.

As to claims 93 and 94, the material to be ingested is carbohydrates (see column 5, line 59).

As to claim 95, the method includes determining a duration of how long a previously infused amount of liquid will remain active in the body based upon a duration factor; and adjusting the estimate of the bolus amount of fluid to be infused based upon the determined duration, see column 5, lines 51-61.

4. Claims 84 and 86-88 and 91-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki 4,826,810.

Aoki discloses a method intended for use in an infusion device, the method comprising inputting externally supplied values and an estimate of a material to be ingested by the body into the programmer to estimate the bolus amount of fluid to be infused based upon the estimate of the material to be ingested by the body (see column 6, lines 63-68), wherein the externally supplied values and the estimate of the material

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to be ingested by the body are input using the at least one data input device (18); calculating an estimate of the bolus amount of fluid to be infused into the body based upon the externally supplied values and the estimate of the material to be ingested by the body (see column 5, lines 55-62); and providing the estimate of the bolus amount of fluid to the user for use with the infusion device (see column 5, lines 56-57.)

As to claim 86, there is at least one button (18) to interface with the processor.

As to claim 87, disclosed is the step of using the bolus estimator to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 6, lines 55-61 and column 8, lines 9-16.)

As to claim 88, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, (see column 5, lines 59-61.)

As to claim 91, the step of programming the infusion device to infuse the estimate of the bolus amount of fluid into the body is disclosed, see column 6, line 43.

As to claim 92, the bolus estimator is considered to include a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. An on/off button for example is considered a lockout as claimed.

As to claims 93 and 94, the material to be ingested is carbohydrates (see column 5, line 60.)

As to claim 95, the method includes determining a duration of how long a previously infused amount of liquid will remain active in the body based upon a duration

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factor; and adjusting the estimate of the bolus amount of fluid to be infused based upon the determined duration, see column 5, lines 55-61 and column 57-63.

5. Claims 84 and 86-88 and 91-95 are rejected under 35 U.S.C. 102(e) as being anticipated by Tetzlaff, 6,556,963.

Tetzlaff discloses a method intended for use in an infusion device, the method comprising inputting externally supplied values and an estimate of a material to be ingested by the body into the programmer to estimate the bolus amount of fluid to be infused based upon the estimate of the material to be ingested by the body (see column 6, lines 59-63), wherein the externally supplied values and the estimate of the material to be ingested by the body are input using the at least one data input device (124); calculating an estimate of the bolus amount of fluid to be infused into the body based upon the externally supplied values and the estimate of the material to be ingested by the body (see column 5, lines 15-24); and providing the estimate of the bolus amount of fluid to the user for use with the infusion device (see column 5, lines 15-24.)

As to claim 86, there is at least one button (124) to interface with the processor.

As to claim 87, disclosed is the step of using the bolus estimator to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 5, lines 15-24.)



As to claim 88, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, (see column 5, lines 15-24.)

As to claim 91, the step of programming the infusion device to infuse the estimate of the bolus amount of fluid into the body is disclosed, see column 5, line 23-24.

As to claim 92, the bolus estimator is considered to include a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. An on/off button for example is considered a lockout as claimed.

As to claims 93 and 94, the material to be ingested is carbohydrates (see column 5, line 19.)

As to claim 95, the method includes determining a duration of how long a previously infused amount of liquid will remain active in the body based upon a duration factor; and adjusting the estimate of the bolus amount of fluid to be infused based upon the determined duration, see column 5, lines 21-23.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al., 5,822,715, in view of Welch et al., 5,319,363.

Worthington et al. discloses the invention substantially as claimed (see above), except for a touchscreen.

Welch et al. discloses a touchscreen as a means for interacting with a processor, see column 7, line 12. It would have been obvious to provide a touchscreen in the Worthington et al. device, as taught by Welch et al., as a known means for interacting with a processor.

7. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franetzki et al., 4,282,872, in view of Welch et al., 5,319,363.

Franetzki et al. discloses the invention substantially as claimed (see above), except for a touchscreen.

Welch et al. discloses a touchscreen as a means for interacting with a processor, see column 7, line 12. It would have been obvious to provide a touchscreen in the Franetzki et al. device, as taught by Welch et al., as a known means for interacting with a processor.

8. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki 4,826,810, in view of Welch et al., 5,319,363.

Aoki discloses the invention substantially as claimed (see above), except for a touchscreen.

Welch et al. discloses a touchscreen as a means for interacting with a processor, see column 7, line 12. It would have been obvious to provide a touchscreen in the Aoki device, as taught by Welch et al., as a known means for interacting with a processor.

9. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tetzlaff, 6,556,963, in view of Welch et al., 5,319,363.

Tetzlaff discloses the invention substantially as claimed (see above), except for a touchscreen.

Welch et al. discloses a touchscreen as a means for interacting with a processor, see column 7, line 12. It would have been obvious to provide a touchscreen in the Tetzlaff device, as taught by Welch et al., as a known means for interacting with a processor.

### ***Response to Arguments***

Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive.

Applicant argues on page 10 that, with respect to the rejections under 35 USC 112, second paragraph, the claims recite a method which is intended for use in an infusion system. However, Examiner asserts that Applicant has not claimed that the

method is intended for use in an infusion system. In short, the claims recites "[i]n an infusion system comprising...., a method of estimating a bolus amount....the method comprising the steps of...." Applicant's claim is not a grammatically correct sentence, and thus is indefinite.

Applicant argues that although Worthington discloses a method of calculating an insulin dose, it is not based upon an estimate of a material to be ingested by the body.

In response, as to the rejected claims 84-88 and 92-95, Worthington anticipates the claims as written. Examiner points to column 14, lines 28-31, which states that a number of grams of carbohydrates to be consumed is calculated, and lines 45-48, which states that a carbohydrate supplement may be recommended based on the calculation. Examiner would like to note that in these claims, Applicant has not indicated that the fluid to be infused is insulin.

### ***Conclusion***

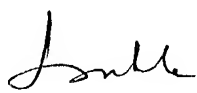
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 

  
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02/23/04